

Listing of the Claims

Claims 1-35 (canceled)

Claim 36 (currently amended): A method of treating a human patient suffering from a disease or condition comprising administering to a patient in need thereof a pharmaceutical composition at a monthly dose of about 0.25 mg up to about 60 mg of paclitaxel/kg body weight of the patient, wherein the pharmaceutical composition comprises a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%.

Claim 37 (previously presented): The method of claim 36, wherein the monthly dose is about 0.5 mg up to about 30 mg paclitaxel/kg body weight.

Claim 38 (previously presented): The method of claim 37, wherein the monthly dose is about 1.0 mg up to about 15 mg paclitaxel/kg body weight.

Claim 39 (previously presented): The method of claim 37, wherein the monthly dose is about 1 to about 7.5 mg/paclitaxel/kg body weight.

Claim 40 (previously presented): The method of claim 36, wherein the monthly dose is about 20 to about 60 mg/paclitaxel/kg body weight.

Claim 41 (previously presented): The method of 36, wherein administering the cationic liposomal preparation comprises administering at least once daily.

Claim 42 (currently amended): The method of claim 36, wherein administering the cationic liposomal preparation comprises administering a plurality of times during a month period, and wherein each administration is separated by an interval of between one day and 3 weeks.

Claim 43 (previously presented): The method of claim 36, wherein administering the cationic liposomal preparation comprises administering

- (i) at least 3 times or 3-5 times in a first week, followed by an interval of 1-3 weeks without administration, and optionally one or several repeats of this protocol;
- (ii) once in a first week followed by an interval of at least one week or 1-3 weeks, without administration, and optionally one or several repeats of this protocol;
- (iii) once in a week for one week or several successive weeks; or
- (iv) a combination of (i), (ii) and/or (iii).

Claim 44 (currently amended): A method of treating a human patient suffering from a disease or condition with a combination therapy comprising administering to a patient in need thereof a pharmaceutical composition at a monthly dose of about 0.25 mg up to about 60 mg of paclitaxel/kg body weight of the patient, wherein the pharmaceutical composition comprises ~~comprising~~ a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%, wherein the composition is administered simultaneously, separately, or sequentially with an effective dose of at least one further active agent and/or heat and/or radiation and/or cryotherapy.

Claim 45 (previously presented): The method of claim 44, wherein the composition is administered simultaneously with an effective dose of at least one further active agent.

Claim 46 (previously presented): The method of claim 36, wherein the cationic liposomal preparation comprises paclitaxel in an amount of at least about 2 mole% to about 8 mole%.

Claim 47 (previously presented): The method of claim 36, wherein the cationic liposomal preparation comprises paclitaxel in an amount of about 2.5 mole% to about 3.5 mole%.

Claim 48 (previously presented): The method of claim 36, wherein the cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel.

Claim 49 (previously presented): The method of claim 36, wherein the cationic liposomal preparation comprises substantially no paclitaxel crystals.

Claim 50 (previously presented): The method of claim 36, wherein the condition is an angiogenesis-associated condition.

Claim 51 (currently amended): The method of claim 50, wherein the disease or condition is selected from the group consisting of a wound healing, cancer, an inflammatory disease or a chronic inflammatory disease such as rheumatoid arthritis, dermatitis, psoriasis and or endometriosis.

Claim 52 (currently amended): A method of treating or preventing a disorder associated with and/or accompanied by occurrence of drug resistant cells, such as drug resistant tumors comprising administering to a patient in need thereof a pharmaceutical composition at a monthly dose of about 0.25 mg up to about 60 mg of paclitaxel/kg body weight of the patient, wherein the pharmaceutical composition comprises ~~comprising~~ at least one cationic lipid from about 30 mole% to about 99.9 mole%, an active agent in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%.

Claim 53 (previously presented): The method of claim 52, wherein the method is a second or third line treatment for cancer.

Claim 54 (previously presented): The method of claim 52, wherein the cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel.

Claim 55 (currently amended): A method of treating or preventing metastasis formation in a human patient, such as an onset and/or progression, particularly associated with and/or accompanied by a tumor disorder comprising administering a pharmaceutical composition at a monthly dose of about 0.25 mg up to about 60 mg of paclitaxel/kg body weight of the patient, wherein the pharmaceutical composition comprises ~~comprising~~ a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, an active agent in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%.

Claim 56 (previously presented): The method of claim 55, wherein the method treats or prevents liver metastasis formation.

Claim 57 (currently amended): A method of treating a human patient with a combination therapy comprising administering to a patient in need thereof a pharmaceutical composition at a monthly dose of about 0.25 mg up to about 60 mg of paclitaxel/kg body weight of the patient, wherein the pharmaceutical composition comprises ~~comprising~~ a cationic liposomal preparation comprising at least one cationic lipid from about 30 mole% to about 99.9 mole%, an active agent in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole% for manufacturing a pharmaceutical composition, wherein the composition is administered simultaneously, separately, or sequentially with an effective dose of at least one further active agent and/or heat and/or radiation and/or cryotherapy against metastasis onset and/or progression, e.g. associated with and/or accompanied by the tumors.

Claim 58 (previously presented): The method of claim 57, wherein the composition is administered simultaneously with an effective dose of at least one further active agent.

Claim 59 (previously presented): The method of claim 52, wherein the active agent is selected from a cytotoxic or cytostatic substance such as an anti-tumor or an anti-endothelial cell active substance, a chemotherapeutic agent or an immunological active substance.

Claim 60 (previously presented): The method of claim 55, wherein the cationic liposomal preparation comprises 50:47:3 mole% of DOTAP, DOPC and paclitaxel.

Claim 61 (currently amended): The method of claim 55, wherein the active agent is selected from the group consisting of ~~a taxane, a camptothecin, a statin, a depsipeptide, thalidomide, other agents interacting with microtubuli such as discodermolide, laulimalide, isolaulimalide, eleutherobin, Sarcodictyin A and B, and in a most preferred embodiment it is selected from~~ paclitaxel, docetaxel, and camptothecin ~~or any derivative thereof~~.

Claim 62 (previously presented): The method of claim 44, wherein the further active agent is an anti-endothelial cell active substance, an anti-tumor active substance, a chemotherapeutic agent, an immunological active substance, a compound that reduces or eliminates hypersensitivity reactions or a chemosensitizer.

Claim 63 (currently amended): The method of claim 44, wherein the further active agent is selected from the group consisting of ~~antineoplastic agents especially antimitotic agents like~~

paclitaxel, ~~alkylating agents especially platinum containing compounds like cisplatin, carboplatin, DNA topoisomerase inhibiting agents like camptothecin or doxorubicin, RNA- / DNA antimetabolites, especially 5-fluorouracil or and gemcitabine and other compounds having antitumor activity.~~

Claim 64 (currently amended/withdrawn): The method of claim 62, wherein the compound that reduces or eliminates hypersensitivity reactions is selected from the group ~~comprising~~ consisting of steroids, antihistamines, H2 receptor antagonists, and combinations thereof in a sufficient amount to prevent fatal anaphylactic reactions.

Claim 65 (withdrawn): The method of claim 63, wherein the compound is selected from the group consisting of Ranitidine, Dexamethasone, Diphenhydramine, Famotidine, Hydrocortisone, Clemastine, Cimetidine, Prednisolone, Chlorpheniramine, Chlorphenamine, Dimethindene maleate, and Promethazine.

Claim 66 (withdrawn): The method of claim 62, wherein the chemosensitizer is selected from the group consisting of cell cycle modulators, substances that revert a drug resistance like verapamil, vasoactive substances like anti-hypertensive drugs, and substances that modify interactions of cationic liposomes with blood components like protamine.

Claim 67 (currently amended): The method of claim 36 for the treatment of cancer, wherein the disease is selected from the group consisting of especially pancreatic cancer, inoperable pancreatic cancer, gastro-intestinal cancer, lung cancer, colorectal or gastric cancer, breast cancer, prostate cancer and melanoma.

Claim 68 (previously presented): The method of claim 36, wherein the cationic liposomal preparation comprises liposomes having an average particle diameter from about 25 nm to about 500 nm, preferably about 100 nm to about 300 nm.

Claim 69 (currently amended): The method of claim 36, wherein the cationic liposomal preparation is administered ~~systemically, preferably~~ intravenously.

Claim 70 (currently amended): A method of treating a disease or condition comprising administering to a human patient in need thereof a pharmaceutical composition at a monthly dose

of about 9 mg up to about 2337 mg of paclitaxel/m² body surface of the human patient, wherein the pharmaceutical composition comprises at least one cationic lipid from about 30 mole% to about 99.9 mole%, paclitaxel in an amount of at least about 0.1 mole% and at least one neutral and/or anionic lipid from about 0 mole % to about 70 mole%.

Claim 71 (new): The method of claim 55, wherein the active agent is paclitaxel.

Claim 72 (new): The method of claim 36, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.

Claim 73 (new): The method of claim 44, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.

Claim 74 (new): The method of claim 52, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.

Claim 75 (new): The method of claim 55, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.

Claim 76 (new): The method of claim 57, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.

Claim 77 (new): The method of claim 70, wherein the cationic liposomal preparation comprises at least one neutral and/or anionic lipid from about 1 mole % to about 70 mole %.